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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/453,350	05/30/95	HELDIN	C 0054.009

EXAMINER

18N2/0708

CHIRON CORPORATION
INTELLECTUAL PROPERTY R440
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BROWN, J.

ART UNIT	PAPER NUMBER
1812	31

DATE MAILED: 07/08/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4/10/97

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 25-27, 43-54 is/are pending in the application.
Of the above, claim(s) 46-54 is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 25-27, 43-45 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☒ Claim(s) 25-27, 43-54 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 26, 27
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

DETAILED ACTION

Election/Restriction

1. Newly submitted claims 46-54 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

2. New claims 46-54 are directed to a method of treating wounds with PDGF AA while claims 25-27 are drawn to the PDGF AA protein and new claims 43-45 are drawn to a pharmaceutical composition of PDGF AA. The invention of claims 46-54 is a process of using the product of claims 25-27 and 43-45. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product can be used other than to treat wounds, such as to produce antibodies to PDGF AA for diagnostic use, for instance.

3. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 46-54 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Amendments and Arguments

4. The declaration filed on 2 May 1997 under 37 CFR 1.131 is sufficient to overcome the Betsholtz and Murray references.

5. The rejection of claims 25-27 under 35 USC 112, first paragraph, is withdrawn in view of Applicant's arguments. The rejection of claims 25-27 under 35 USC 102(a) over Betsholtz and under 35 USC 102(e) over Murray is withdrawn in view of declaration filed under 37 CFR 1.131.

Claim Rejections - 35 USC § 102

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 25-27 and 43-45 are rejected under 35 U.S.C. 102(b) as being anticipated by Heldin et al. (Nature 319, 511-514, 1986).

The rejection of claims 25-27 is maintained for reasons of record set forth in Paper No. 28, pages 4-5. Heldin et al. also anticipate the pharmaceutical composition of claims 43-45 because Heldin et al. disclose that the purified PDGF AA (ODGF) is tested for growth promoting activity of cells (Fig. 1 legend, p. 512). Since the PDGF AA would be in cell culture medium for this test, and since cell culture medium is a pharmaceutically acceptable excipient, Heldin et al. anticipates a pharmaceutical composition of PDGF AA.

8. Applicant's arguments filed 2 May 1997 have been fully considered but they are not persuasive.

Applicant argues that the claims distinguish over Heldin et al. because the claims recite that the PDGF AA is produced recombinantly and is free of other human proteins. Applicant asserts that the protein isolated by Heldin et al. is isolated by conventional protein chemistry techniques and would inherently contain other human protein contaminants. These arguments are

not found persuasive because the protein isolated by Heldin et al. appears to be highly pure, since there are no bands other than PDGF AA in the protein preparation which are visible after SDS PAGE and silver staining of the gel (see Fig. 1, p. 512). It is well-known that silver staining is one of the most highly sensitive methods of determining whether there are any protein contaminants in a preparation. In addition, Heldin et al. state that no other amino acid sequence was obtained from the purified PDGF AA preparation (p. 512). Amino acid sequence analysis is also a highly sensitive method of determining whether a protein sample is homogeneous. Applicant argues that recombinant production of PDGF AA is advantageous because recombinant PDGF AA is devoid of other human proteins and potential viral contamination. This argument is unpersuasive because, as discussed above, the PDGF AA protein preparation taught by Heldin et al. appears to be devoid of other human proteins and viral contamination as well, since the protein was derived from the conditioned medium of cells grown in a laboratory (Fig. 1 legend, p. 512), which would be highly unlikely to be contaminated with virus. Lastly, Applicant argues that the purity of a preparation can be used to impart patentability over prior art references disclosing heterogeneous mixtures; however, in this case, the prior art protein is homogeneous, not heterogeneous, absent evidence to the contrary, and thus this argument is unpersuasive as well.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Brown whose telephone number is (703) 308-3668. The examiner can normally be reached on Mondays through Thursdays and on alternate Fridays from 8:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957.

Official papers filed by fax should be directed to (703) 305-4242 or to (703) 305-3014. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to **[stephen.walsh@uspto.gov]**.

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

KEB
2 July 1997

Stephen Walsh

STEPHEN WALSH
SUPERVISORY PATENT EXAMINER
GROUP 1800